

**REMARKS**

Claims 1-8, 14-18, 26-28 and 30-35 are pending in the present application. Amendments to the claims correct antecedent basis, Markush language, or dependency issues. Applicants assert that the amendments do not add new matter.

1. Applicants note with appreciation the withdrawal of the rejections of record under 35 U.S.C. §§ 103 and 112, first paragraph. Applicants further note with appreciation the Examiner's allowance of claims 1 and 3-8.

2. Claim 29 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have cancelled claim 29, thereby obviating the rejection, and respectfully request reconsideration and withdrawal of the rejection.

3. Claims 14-17, 26-27, and 29-35 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The Examiner states that the preamble of claims 14 and 18 is drawn to a method of screening for bacteria in a donor tissue, whereas the body of the claim refers to donor blood. Applicants have carefully reviewed the claim language of claims 14, 17, and 18, and believe that the Examiner intended to state that claim 17 was indefinite, rather than claim 18 as Applicants did not observe the recitation of the phrase "donor blood or blood product" in claim 18. Applicants have amended claims 14 and 17 to correctly recite donor tissue in the body of the claim.
- b) The Examiner states at page 4 of the Office Action that claim 27 recites alternative limitations which are improperly expressed. Applicants have amended claim 27 as suggested by the Examiner to conform with Markush language.
- c) The Examiner states at page 4 of the office action that claim 29 lacks proper antecedent basis. Applicants have cancelled claim 29, thereby rendering the

rejection moot. Nonetheless, the claims recite donor blood, blood product, or tissue found to be free of clinically relevant amounts of bacteria as safe/useful for transfer to a recipient. Claim 29 recited the limit of clinically relevant amount of bacteria, where if the levels were greater than  $1 \times 10^6$  CFU/mL, the levels were clinically relevant. Thus, Applicants assert that claim 29 was definite.

- d) The Examiner states at page 4 of the Office Action that claim 29-35 are unclear due to the recitation of donor blood or blood products. Applicants submit that claim 34 depends on claim 26, which has not been cited by the Examiner as being indefinite and request clarification as to whether claim 34 was intended to be rejected. Claim 33 depends on claim 27, which has been amended by applicant as stated above, thus, Applicants submit that claim 33 is definite. Claims 29-35 depend on claims 14, 17, and 18, which recite methods of screening donor tissue. Applicants have cancelled claim 29, amended claims 30-35 to depend on claims recitation of donor blood, blood products, or tissue, thus, rendering the claim definite.

Applicant submit that the claims are currently recited are definite and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

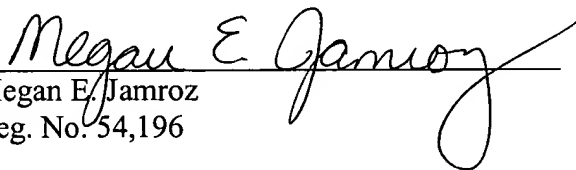
**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

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